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Perioperative ischemic evaluation study (POISE study)

Submission date	Recruitment status	[_] Prospectively registered
19/08/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/02/2009	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.phri.ca/poise.htm

Contact information

Type(s)
Scientific

Contact name
Dr Philip Devereaux

Contact details
Clinical Epidemiology & Biostatistics
McMaster University Health Sciences Centre
Room 2C8, 1200 Main Street West
Hamilton, Ontario
Canada
L8N 3Z5
+1 905 525 9140 ext. 22063
philipj@mcmaster.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00182039

Secondary identifying numbers
MCT-50851, ACTRN012605000308695

Study information

Scientific Title

Acronym
POISE

Study objectives
Perioperative metoprolol will reduce the 30 day risk of major cardiovascular events in patients undergoing noncardiac surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McMaster University Research Ethics Board approved on 25th April 2002

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular

Interventions
Patients will be randomly assigned to either the experimental intervention of oral metoprolol or the control intervention, a placebo. Patients will receive their first dose of metoprolol CR or placebo two to four hours pre-operatively at a strength of 100 mg (1/2 of a 200 mg tablet). Patients will then receive their second dose of their assigned intervention during the first 6 hours or at 6 hours post surgery. Twelve hours after the second post-op dose, patients will start taking a daily dose of 200 mg of either metoprolol CR or placebo for a duration of 30 days post surgery.

For further information, please contact Dr Devereaux at the address listed below or Dr Homer Yang at Ottawa Hospital (hyang@ottawahospital.on.ca).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Metoprolol

Primary outcome measure
Cardiac death at 30 days, nonfatal myocardial infarction (MI), and nonfatal cardiac arrest

Secondary outcome measures
1. Length of hospital stay
2. Length of stay in an ICU/CCU
3. Revascularisation procedures (i.e. coronary artery bypass surgery and percutaneous transluminal coronary angioplasty)
4. Pulmonary oedema
5. Clinically significant atrial fibrillation
6. Stroke
7. Total mortality
8. Rehospitalisation for cardiac reasons
9. Myocardial infarction
10. Nonfatal cardiac arrest
11. Cardiovascular mortality
12. Clinically significant hypotension
13. Clinically significant bradycardia

Overall study start date
01/09/2002

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Greater than or equal to 45 years of age, either sex
2. Have an expected length of stay greater than or equal to 24 hours
3. Fulfill any one of the following six criteria:
3.1. Coronary artery disease
3.2. Peripheral vascular disease
3.3. History of stroke due to atherothrombotic disease
3.4. Hospitalisation for congestive heart failure within 3 years of randomisation
3.5. Undergoing major vascular surgery
3.6. Any three of the following seven criteria: scheduled for high risk surgery (i.e. intraperitoneal or intrathoracic), emergency/urgent surgery, any history of congestive heart failure, history of a

transient ischaemic attack (TIA), diabetes and currently on an oral hypoglycaemic agent or insulin therapy, preoperative serum creatinine greater than 175 µmol/l (greater than 2.0 mg/dl), or age greater than 70 years
4. Are able to give written consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10,000

Key exclusion criteria
1. Contradiction to metoprolol including any of the following: significant bradycardia (heart rate less than 50 beats per minute); second or third degree heart block without a pacemaker, asthma that has been active within the last decade, and history of chronic obstructive pulmonary disease (COPD) with bronchospasm on pulmonary function tests
2. Clinical plan to use a beta-blocker preoperatively or during the first 30 postoperative days prior adverse reaction to a beta-blocker
3. Coronary artery bypass graft (CABG) surgery with complete revascularisation in the preceding 5 years and no evidence of cardiac ischaemia since the CABG surgery
4. Patients undergoing low risk surgical procedures (potential examples include transurethral procedures [transurethral prostatectomies {TURPs}, stone baskets etc.], ophthalmologic procedures under topical or regional anaesthesia [cornea transplants, cataract surgery etc.], and surgeries with limited physiological stresses [digital re-implantation, nerve repairs etc.])
5. Concurrent use of verapamil
6. Prior enrolment in this trial

Date of first enrolment
01/09/2002

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Australia

Canada

Study participating centre
Clinical Epidemiology & Biostatistics
Hamilton, Ontario

Canada
L8N 3Z5

Sponsor information

Organisation
McMaster University (Canada)

Sponsor details
1200 Main Street West
Hamilton, Ontario
Canada
L8N3Z5
+1 905 521 2100 ext 22465
townsend@mcmaster.ca

Sponsor type
University/education

Website
http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-50851)

Funder Name
National Health and Medical Research Council (NHMRC) (Australia)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Funder Name
Australia Clinical Trials Grant (Australia)

Funder Name
British Heart Foundation (UK)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Astra Zeneca (International)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	31/05/2008	Yes	No